

DETAILED ACTION

Request for Continued Examination

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 11/12/2010 has been entered.

Status of Application/Amendment/Claims

Applicant's response filed 11/12/2010 has been considered. Rejections and/or objections not reiterated from the previous office action mailed 07/22/2010 are hereby withdrawn. The following rejections and/or objections are either newly applied or are reiterated and are the only rejections and/or objections presently applied to the instant application. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

With entry of the amendment filed on 11/12/2010, claims 1-8, 11, 19 and 58-60 are pending and currently under examination in the application.

New Rejections Necessitated by Claim Amendments

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the

art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1 -8, 11, 19 and 58-60 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a new matter rejection.

Claims 1 -8, 11, 19 and 58-60 are drawn to an isolated intron comprising an artificial intron comprising "a gene silencing effector"

The specification in paragraph 0063 disclose inserts having DNA templates for RNA. Applicant points to Figure 1 for support which shows RNA inserts such as sense stRNA, antisense RNA, hairpin siRNA and ribozymes. The specification does not define what an effector is nor does the specification disclose any language describing "a gene silencing effector". If Applicant believes that such support is present in the specification and claimed priority documents, Applicant should point, with particularity, to where such support is to be found.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1 -8, 11, 19 and 58-60 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

To satisfy the written description requirement, MPEP §2163 states, in part "...a patent specification must describe the claimed invention in sufficient detail that one skilled in the art can reasonably conclude that the inventor had possession of the claimed invention." Moreover, the written description requirement for a genus may be satisfied through sufficient description of a representative number of species by "...disclosure of relevant, identifying characteristics, i.e., structure or other physical and/or chemical properties, by functional characteristics coupled with a known or disclosed correlation between functional and structure, or by a combination of such identifying characteristics, sufficient to show the applicant was in possession of the claimed genus."

The claims are drawn to a broad genus of gene silencing effectors that when released in the cell the function of any target gene is silenced.

The instant claims and specification fail to provide adequate written description of broad genus of gene silencing effectors. The term "effector" is not defined and the skilled artisan would not know which structure is encompassed such as to have the claimed function. While the specification discloses RNA inserts such as an antisense, sense and hairpin RNA targeted to GFP and reduction of expression, these 3 molecules

targeted to one gene do not adequately describe such nucleic acid molecules so that one of ordinary skill in the art reading the application at the time of filing could envision the RNA effector for any particular gene with the function of silencing the expression. In fact, as explained below with respect to siRNA and hairpin siRNA, the art recognizes that the design of siRNA and shRNA is crucial for the success of gene expression inhibition using short interfering dsRNA.

Documented reports show that variability exists within the genus. Holen et al. (2002) *Nucleic Acids Res.* 30:1757–1766, for example, report that siRNAs directed against the same target varied widely in their silencing efficiencies (pp. 1759-1760). "...despite the minimal sequence and position differences between these siRNAs, they displayed a wide range of activities" (page 1758). "Our results indicate that susceptible siRNA target sites in some human genes may be rare." (page 1765). "At present, however, the factors determining the differences in siRNA efficiency remain unclear." (page 1761).

MPEP §2163 states, in part: "[A] patentee of a biotechnological invention cannot necessarily claim a genus after only describing a limited number of species because there may be unpredictability in the results obtained from species other than those specifically enumerated. A patentee will not be deemed to have invented species sufficient to constitute the genus by virtue of having disclosed a single species when ... the evidence indicates ordinary artisans could not predict the operability in the invention of any species other than the one disclosed. *In re Curtis*, 354 F.3d 1347, 1358, 69 USPQ2d 1274, 1282 (Fed. Cir. 2004).

Accordingly, the specification does not adequately allow persons of ordinary skill in the art to recognize that applicant(s) were in possession of the entire genus of RNA gene silencing effectors that silence each and every gene.

An applicant shows possession of the claimed invention by describing the claimed invention with all of its limitations using such descriptive means as words, structures, figures, diagrams, and formulas that fully set forth the claimed invention. *Lockwood v. American Airlines, Inc.*, 107 F.3d 1565, 1572, 41 USPQ2d 1961, 1966 (Fed. Cir. 1997).

Response to Arguments

Claim Rejections - 35 USC § 103

The rejection of claims 58-60 under 35 U.S.C. 103(a) as being unpatentable over Cheo et al. (US Patent No. 7,393,632), Mitchell et al. (of record cited on form 892 mailed 03/11/2008), Krawczak et al. (Hum Genet 1992, Vol. 90: 41-54 of record PTO Form 892 mailed 03/11/2008), Zhuang et al. (PNAS Vol. 86: 2752-2756 of record PTO Form 892 mailed 03/11/2008), Coolidge et al. (of record cited on 892 mailed 01/23/2009) and Bennett et al. (US Patent No. 6,710,174) is withdrawn.

Claim Rejections - 35 USC § 102

The rejection of claims 1, 2, 3, 7, and 11 under 35 U.S.C. 102(e) as being anticipated by Cheo et al. (US Patent No. 7,393,632) is withdrawn.

Applicant's arguments have been fully considered but they are not persuasive. Applicant argues Cheo et al. fails to disclose an isolated RNA comprising an artificial intron RNA that is released into a cell thereby silencing the function of a target gene.

Claim Rejections - 35 USC § 103

The rejection of claims 1-8, 11, and 19 under 35 U.S.C. 103(a) as being unpatentable over Cheo et al. (US Patent No. 7,393,632), Mitchell et al. (of record cited on form 892 mailed 03/11/2008), Krawczak et al. (Hum Genet 1992, Vol. 90: 41-54 of record PTO Form 892 mailed 03/11/2008), Zhuang et al. (PNAS Vol. 86: 2752-2756 of record PTO Form 892 mailed 03/11/2008, Coolidge et al. (of record cited on 892 mailed 01/23/2009) and Bennett et al. (US Patent No. 6,710,174) is withdrawn.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kimberly Chong whose telephone number is 571-272-3111. The examiner can normally be reached Monday thru Friday between 7-4 pm.

If attempts to reach the examiner by telephone are unsuccessful please contact the SPE for 1635 Heather Calamita at 571-272-2876. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within

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/Kimberly Chong/
Primary Examiner
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